

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

BAILEY SILVERMAN, *et al.*,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Defendants.

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CIVIL ACTION H-10-1952

MEMORANDUM OPINION & ORDER

Pending before the court is defendant Capsugel, Inc.’s motion to exclude the opinions of plaintiffs’ experts on general and specific causation and for summary judgment. Dkt. 70. Upon consideration of the motion, the response, the reply, oral argument presented by counsel, and the applicable law, the motion is DENIED.

BACKGROUND

In September 2008 Bailey Silverman switched her blood pressure medication to the generic version, called Taztia XT, manufactured by defendants Watson Pharmaceuticals, Inc. and Watson Pharma, Inc. (collectively the “Watson defendants”) using hard gelatin capsules made by defendant Capsugel. Dkt. 70. She began to suffer symptoms such as difficulty walking, fatigue, muscle weakness, and a metallic taste in her mouth. Dkt. 93. Her symptoms worsened and in December 2008 she went to the emergency room. *Id.* She was treated by Dr. Fleming, a neurologist. Dkt. 70. He could not determine the cause of her problems but thought she might be having a stroke, or Bell’s Palsy. *Id.* However, tests showed elevated levels of arsenic in her urine. *Id.* Dr. Fleming performed other tests and determined that she was suffering distal polyneuropathy. Dkt. 93. Dr. Fleming

treated her with steroids with no success. *Id.* Mrs. Silverman's husband, Dr. Louis Silverman, a thoracic surgeon, began to suspect that the elevated arsenic in her urine might be the cause. *Id.* So, when her symptoms worsened again, he spoke with Dr. Joseph Varon—a neurologist well versed in the area of arsenic poisoning. *Id.*

Upon Dr. Varon's advice, Mrs. Silverman was hospitalized in January 2009. Dr. Varon suspected she was suffering from arsenic poisoning. Dkt. 70, Ex. A-1. He brought in Dr. Vincent Virgadamo to assist in treating Mrs. Silverman. *Id.* Dr. Varon ran tests that ruled out other possible causes of her symptoms. *Id.* Believing that her condition was life-threatening, Dr. Varon began treating her with chelation therapy. *Id.* Chelation therapy is itself life threatening but is the only known cure for arsenic poisoning. *Id.* She survived the painful two-week course and the levels of arsenic in her system dropped to normal. Dkt. 93, Ex. F. However, she continues to suffer after effects of the poisoning. *Id.* She has peripheral neuropathy, joint pain, numbness, fatigue, and difficulty performing tasks requiring fine motor skills. *Id.*

At the same time that Mrs. Silverman began treatment with Dr. Varon, she discontinued taking the Taztia XT. *Id.* Dr. Silverman filed a complaint with the FDA reporting that Mrs. Silverman had suffered degeneration of her body from taking one of her medications. Dkt. 70, Ex. A-3. The FDA collected samples from the Walgreen's pharmacy the Silvermans used but could not determine the specific drug lot used by Mrs. Silverman. *Id.* at A-8. Dr. Silverman sent 44 Taztia XT capsules to the FDA for testing. *Id.* Additionally, Dr. Silverman sent samples of the Taztia XT to Kappa Laboratories, Inc. for testing. Dkt. 93. Kappa sent the pills to an affiliate, Advanced Environmental Laboratories ("AEL"). *Id.* Plaintiffs retained Dr. Ernest Lykissa—a forensic toxicologist—to testify regarding the results of the lab test results and Mrs. Silverman's condition. Dkt. 70, Ex A-10.

Capsugel now moves the court to exclude the expert testimony of Dr. Varon and Dr. Lykissa and to grant summary judgment for defendants because plaintiffs fail to present an issue of fact regarding causation.

I. Motion to Exclude

Capsugel moves to exclude the causation testimony of plaintiffs' experts—Dr. Joseph Varon, and Dr. Ernest Lykissa. As a threshold matter, Capsugel asks the court to conflate federal procedural law governing the admissibility of expert testimony with Texas substantive law regarding the levels of proof required to demonstrate causation in a toxic tort case. And perhaps the legal sufficiency question could be considered part of the relevance prong of *Daubert*. However, while there is dicta from the Fifth Circuit suggesting that the *Daubert* inquiry and scientific sufficiency under Texas law are coterminous, no consensus exists. *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 381 (5th Cir. 2010). Therefore, the court will address Capsugel's legal sufficiency arguments through the vehicle of the motion for summary judgment rather than on a motion to exclude. And, since all of Capsugel's arguments under this heading go to the subject of legal sufficiency, the motion to exclude is denied.

II. Motion for Summary Judgment

Capsugel moves for summary judgment arguing that plaintiffs have failed to meet the standards under Texas law for general and specific causation.

A. Legal Standard

A motion for summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Carrizales v. State Farm Lloyds*, 518 F.3d 343, 345 (5th Cir. 2008). A fact issue is "material" if its resolution could affect the outcome of the action. *Burrell v. Dr.*

Pepper/Seven Up Bottling Group, Inc., 482 F.3d 408, 411 (5th Cir. 2007). “[A]nd a fact is genuinely in dispute only if a reasonable jury could return a verdict for the [nonmovant].” *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). Ultimately, “[w]here the record taken as a whole could not lead a rational trier of fact to find for the [nonmovant], there is no ‘genuine issue for trial.’” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986).

When the movant bears the burden of proof on an issue, he must establish beyond peradventure *all* of the essential elements of the claims or defenses to warrant judgment in his favor. *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (emphasis in original). But when the movant does not bear the burden of proof on a claim or affirmative defense, he bears the initial burden of production to show an absence of evidence to support the non-movant’s claim. *TIG Ins. Co. v. Sedgwick James*, 276 F.3d 754, 759 (5th Cir. 2002). If the movant makes this showing, the ultimate burden to avoid summary judgment shifts to the non-movant who “must go beyond the pleadings and come forward with specific facts indicating a genuine issue for trial.” *Davis-Lynch, Inc., v. Moreno*, 667 F.3d 539, 550 (5th 2012). Conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation are no substitute for specific facts showing a genuine dispute for trial. *TIG Ins. Co.*, 276 F.3d at 759.

B. Analysis

1. Toxic Tort Causation

Capsugel argues that in order to survive summary judgment, the plaintiffs must meet their burden to show causation pursuant to Texas laws regarding toxic torts. Under Texas law, “causation in toxic tort cases is discussed in terms of general and specific causation.” *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997). “General causation is whether a substance is

capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury.” *Id.*

Capsugel argues that plaintiffs cannot show general causation because the Texas Supreme Court has held that for an epidemiological study to support general causation, it must show a doubling of the risk. Dkt. 70 (citing *Havner*, 953 S.W. 2d at 720–21). Plaintiffs do not directly address Capsugel’s general causation argument, arguing instead that it is almost axiomatic that exposure to *arsenic* would cause *arsenic* poisoning.

Capsugel next argues that plaintiffs cannot show specific causation because their experts do not model the dose of arsenic that Mrs. Silverman received. Capsugel argued at the hearing before the court that *Borg-Warner Corporation v. Flores*, 232 S.W.3d 765 (Tex. 2007) controls in this matter. In that case, Flores—a brake mechanic, who repaired brakes for 35 years brought suit against Borg-Warner, among others, for his alleged asbestosis. *Id.* at 766. Flores was able to demonstrate that grinding brakes created dust that he inhaled. *Id.* He also could show that in certain instances inhaling asbestos can cause asbestosis. *Id.* at 766–67. Additionally, there was no argument that the brakes manufactured by Borg-Warner contained asbestos. *Id.* at 766. Flores knew approximately how many brake pads he ground that were manufactured by Borg-Warner during the time period in question. *Id.* And, he knew the range of asbestos contained in each pad. *Id.* The Texas Supreme Court reversed the trial and appellate courts, saying:

This record, however, reveals nothing about how much asbestos Flores might have inhaled. He performed about fifteen to twenty brake jobs a week for over thirty years, and was therefore exposed to “some asbestos” on a fairly regular basis for an extended period of time. Nevertheless, absent any evidence of dose, the jury could not evaluate the quantity of respirable asbestos to which Flores might have been exposed or whether those amounts were sufficient to cause asbestosis. Nor did Flores introduce evidence regarding what percentage of that indeterminate amount may have originated in Borg–Warner products. We do not know the asbestos content of other brands of brake pads or how much of Flores's exposure came from grinding new pads

as opposed to blowing out old ones. There were no epidemiological studies showing that brake mechanics face at least a doubled risk of asbestosis. . . . Thus, while some respirable fibers may be released upon grinding some brake pads, the sparse record here contains no evidence of the approximate quantum of Borg–Warner fibers to which Flores was exposed, and whether this sufficiently contributed to the aggregate dose of asbestos Flores inhaled, such that it could be considered a substantial factor in causing his asbestosis.

Id. at 771–72 (internal citations omitted). Although the Court recognized the difficulties in proving asbestos claims and stated that causation “need not be reduced to mathematical precision,” it still required a plaintiff to show “the approximate dose to which the plaintiff was exposed, coupled with evidence that the dose was a substantial factor in causing the asbestos-related disease.” *Id.* at 773. Capsugel concludes that based on *Borg-Warner* all toxic tort cases in Texas must show dosage calculations to support causation.

Plaintiffs counter that *Borg-Warner* clearly sets the standard for asbestos causation, but not causation for all product liability cases. Additionally, they argue that because their expert testimony is based on a differential diagnosis,¹ they do not need dose models. For this proposition, they rely heavily on *Johnson v. Arkema, Inc.*, 685 F.3d 452 (5th Cir. 2012) (interpreting Texas law). In *Johnson* the plaintiff was exposed in two separate incidents to Monobutyltin Trichloride (MBTC) and Hydrochloric acid (HCl) when defendant’s specialized hood designed to vacuum up fumes malfunctioned. *Id.* at 457. After the second incident, he was taken to the emergency room and diagnosed with chemical pneumonitis. *Id.* Much later he was diagnosed with restrictive lung disease and pulmonary fibrosis, which he alleged were also attributable to his exposure to MBTC and HCl..

¹“‘A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.’” *Johnson v. Arkema, Inc.*, 685 F.3d 452, 468 (5th Cir. 2012) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir.1999)) (internal quotation marks omitted).

Id. The district court excluded the plaintiff's two experts on causation. The first expert opined that MBTC and HCl can cause restrictive lung disease and pulmonary fibrosis because the chemicals were part of a class of chemicals that are respiratory irritants. *Id.* at 460. And since other members of the class are known to cause lung injury, the expert inferred that MBTC and HCl also cause lung injury. *Id.* The Fifth Circuit found that the district court had not abused its discretion when it excluded the first expert because

save for highlighting their shared classifications as irritants, [the expert] did not attempt to explain any direct correlation or “fit” between [MBTC and HCl] and the known scientific data concerning exposure to, for example, chlorine, ammonia, or nitric acid vapor. Accordingly, given the diverse chemical structures and toxicities of irritants, . . . we hold that the district court did not abuse its discretion in concluding that [the expert]'s “class of chemicals” theory presented “too great an analytical gap between the data and the opinion proffered.”

Id. at 462 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997)).

The Fifth Circuit treated the second expert differently, noting that the expert had conducted a differential diagnosis. *Id.* at 467–68. The Court went on to explain that a properly supported differential diagnosis could, in some circumstances, constitute evidence of specific causation. *Id.* at 468. However, in *Johnson*, the Court found that because the plaintiff's first expert had failed to prove general causation, the second expert's opinion must also fail. *Id.* at 469 (“Thus, before courts can admit an expert's differential diagnosis, which, by its nature, only addresses the issue of specific causation, the expert must first demonstrate that the chemical at issue is actually capable of harming individuals in the general population, thereby satisfying the general causation standard.”). Plaintiffs contend that because the Court did not require a dosage calculation in *Johnson*, the *Borg-Warner* case is not the blanket rule on causation that defendants urge.

The problem with the parties' arguments on this issue is their characterization of the case as a toxic tort case. The plaintiffs did not plead a toxic tort case. They pled a strict liability

manufacturing defect case. The court does not dispute that courts will sometimes conflate the two, however, as is highlighted in this case, the distinction can be an important one.

A toxic tort is defined as “[a] civil wrong arising from exposure to a toxic substance, such as asbestos, radiation, or hazardous waste.” BLACK’S LAW DICTIONARY 1627 (9th ed. 2009). In *Borg-Warner* and other asbestos exposure cases, there is no allegation that the brake pads were anything other than what the manufacturer intended. The alleged asbestos exposure and resulting injuries are unintended consequences of the product. Some pharmaceuticals arguably fall into this profile if the suit revolves around unintended side-effects of an FDA approved and properly manufactured drug. See *Merck & Co. v. Ernst*, 296 S.W.3d 81 (Tex.App.–Houston [14th Dist.] 2009, pet. denied. And, in these cases, dosage models are reasonably easy to perform since the product specifications are known. But in this case, the product allegedly did not comport with the manufacturer’s standards. For the reasons described below, that puts it in the ambit of Texas law on manufacturing defects, not toxic torts.

2. Manufacturing Defect Causation

In a manufacturing defect case, the product at issue “deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004). In order to meet its burden in a manufacturing defect case, “[a] plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.” *Id.* A specific defect “must be identified by competent evidence and other possible causes ruled out.” *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 42 (Tex. 2007). The Texas Supreme Court defines “producing cause as being a substantial factor in bringing about an injury, and without which the injury would not have occurred.” *Id.* at 46.

“Both direct and circumstantial evidence may be used to establish any material fact.” *Ridgway*, 135 S.W.3d at 601. Circumstantial proof of a defect is often the only evidence available to a plaintiff. *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 848 (Tex. 1979). However, “[t]he inference of defect may not be drawn . . . from the mere fact of a product-related accident.” *Ridgway*, 135 S.W.3d at 602. Instead, “[f]or circumstantial evidence to support an inference that the product was defective, it must provide a reasonable basis for concluding the injury would not ordinarily have occurred *absent* a defect.” *Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 862–63 (Tex.App.–Dallas, 2007, pet. denied) (emphasis added) (citing *Ridgway*, 135 S.W.3d at 604 (Hecht, J., concurring)).


The court recognizes that this case looks, at first blush, like it might fall into the toxic tort paradigm. Arsenic is a poison, like many of the substances involved in toxic tort cases. And, like some pharmaceutical cases, Mrs. Silverman took a prescription drug prescribed for one condition and experienced an adverse reaction. However, unlike those cases, the product here allegedly deviated from the manufacturer’s specifications. And, since Mrs. Silverman did not save pills from each and every lot of pills she ingested, there is no way for her—or anyone else—to show how much arsenic, if any, was in each lot. The previous lots could have had no arsenic or they could have had hundreds of times the level of arsenic found in pills she did save. That is why, in this case, the distinction between Texas law governing toxic tort cases and Texas law governing manufacturing defect cases is critical. And based on the record before the court, the plaintiffs have carried their burden to demonstrate that genuine issues of material fact exist regarding causation. For that reason, summary judgment is not appropriate.

CONCLUSION

Pending before the court is defendant Capsugel's motion to exclude and for summary judgment. Dkt. 70. Upon consideration of the motion, the response, the reply, the summary judgment record, the argument of counsel at oral hearing, and the applicable law, the motion is DENIED.

It is so ORDERED.

Signed at Houston, Texas on April 16, 2013.



Gray H. Miller
United States District Judge